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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO.  |
|---|-------------|----------------------|---------------------|-------------------|
| 09/857,841  | 08/30/2001  | Rong-Xiang Fang      | 2577-109            | 2938              |
| 6449  | 7590        | 12/29/2004           | EXAMINER            |                   |
| ROTHWELL, FIGG, ERNST & MANBECK, P.C.<br>1425 K STREET, N.W.<br>SUITE 800<br>WASHINGTON, DC 20005 |             |                      |                     | HELMER, GEORGIA L |
| ART UNIT  |             | PAPER NUMBER         |                     |                   |
|   |             |                      |                     | 1638              |

DATE MAILED: 12/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                   |              |
|------------------------------|-------------------|--------------|
| <b>Office Action Summary</b> | Application No.   | Applicant(s) |
|                              | 09/857,841        | FANG ET AL.  |
|                              | Examiner          | Art Unit     |
|                              | Georgia L. Helmer | 1638         |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 08 November 2004.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) 1-5, 10-14, 19, 21, 22 and 25-32 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 6-9, 15-18, 20, 23 and 24 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 11 June 2001 is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- See Search Pages ATTACHED to 892*
- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 5December2001.

- 4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: \_\_\_\_\_

**DETAILED ACTION**

***Restriction election***

1. The Office acknowledges the timely receipt of Applicant's restriction election, filed 8 November 2004, in response to the Restriction requirement filed 8 June 2004. Applicant elects Group II claims 6-9, 15-18, 20, 23 and 24, drawn to methods of enhancing production of a protein in a plant comprising fusing a nucleic acid encoding a protein of SEQ ID NO: 4 and a second nucleic acid wherein the fused nucleic acid encodes a fusion protein, without traverse. This restriction is made FINAL.

***Status of the Claims***

2. Claims 1-32 are pending. Claims 1-5, 10-14, 19, 21-22, and 25-32 are nonelected. Claims 6-9, 15-18, 20, 23 and 24 are examined in the instant application.

***Information Disclosure Statement***

3. An initialed and dated copy of Applicant's IDS form 1449, received 5 December 2001, is attached to the instant Office action.

***Claim Rejections - 35 USC § 101***

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 23 and 24 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claims 23 and 24 are drawn to a nucleic acid comprising of SEQ ID NO: 3, and a nucleic acid consisting of SEQ ID NO: These claims read of a product of nature, because no statement is set forth of the nucleic acids being "isolated nucleic acids".

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 6, 7, 9, 15, 16, 17, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,618, 699 in view of WO 96/21018.

The invention described comprises N-terminal fusion constructs, providing enhanced expression in plant systems. The constructs involve the fusion of the N-terminal region of the cucumber mosaic virus coat protein NP14 with a protein of interest.

Claim 6 is drawn to method for enhancing production of a desired protein as part of a fusion protein in a plant cell or plant which comprises inserting a first nucleic acid upstream of a second nucleic acid to form a fused nucleic acid where the first nucleic acid encodes a protein of SEQ ID NO: 4 and wherein the second nucleic acid encodes -a desired protein and further wherein said fused nucleic acid encodes said fusion protein (claim 6).

US 5,618,699 teaches the use of fusion proteins in plants, especially the process whereby a coat protein gene and a foreign gene are directly joined so as to produce a fused protein (US 5,618,699 column 1 lines 19-24). US 5,618,699 further teaches that when the virus coat protein is produced from the virus, the plants produces large

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quantities of the coat protein (column 1, lines 15-18). US 5,618,699 further suggests that viruses of the cucumber mosaic viruses are especially useful in their invention (column 2, lines 49-58) (claim 6). US 5,618,699 teaches the fused protein wherein the foreign gene promoter product is joined to the C-terminal of the coat protein (column 2 lines 44-4).

US 5,618,699 does not teach the protein of SEQ ID NO: 4 or the use of the CaMV 35S promoter.

WO 96/21018 teaches the protein of SEQ ID NO: 4 as the N-terminal sequence of a longer protein (218 amino acids) (see Sequence polypeptide search results result 6, date 6 December 2004). SEQ ID NO: 4 is the N-terminal region of cucumber mosaic virus, this is the N-terminal of the cucumber mosaic virus coat protein .

The CaMV 35S promoter is notoriously well known. (claim 9).The use of the CaMV 35S promoter, is a design choice well within the means of one of ordinary skill without any surprising or unexpected results. Accordingly, the claimed invention is *prima facie* obvious in view of the prior art.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to use of a method of enhanced protein production in a plant wherein large amounts of a protein as part of a fusion protein are produced by fusing a cucumber mosaic virus coat protein gene with a desired coding sequence the cucumber mosaic virus coat protein polypeptide of WO 96/21018. One skilled in the art would have been motivated to use the polypeptide comprising of WO 96/21018, to enhance protein production using the fusion protein of US 5,618,699 , with a reasonable

expectation of success. One skilled in the art would have been motivated to generate the claimed invention with a reasonable expectation of success, especially in, especially in the absence of evidence to the contrary. Accordingly, the claimed invention is *prima facie* obvious in view of the prior art.

6. Claims 6, 7, 8, 9, 15, 16, 17, 18 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,618,699 in view of WO 96/21018, as discussed above for claims 6, 7, 9, 15, 16, 17, and 20, and further in view of US 6,127,601.

US 5,618,699 in view of WO 96/21018 do not teach bases 6-47 of SEQ ID NO: 3.

US 6,127,601 teaches a nucleic acid sequence 100% identical to bases 6-47 of SEQ ID NO: 3 (see annotated nucleic acid search dated 6 December 2004)( US 6,127,601 Figure 3, and column 3, lines 33-36)(claim 8).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to use of a method of enhanced protein production in a plant wherein large amounts of a protein as part of a fusion protein are produced by fusing a cucumber mosaic virus coat protein gene with a desired coding sequence the cucumber mosaic virus coat protein polypeptide of WO 96/21018. One skilled in the art would have been motivated to use the polypeptide comprising of WO 96/21018, to enhance protein production using the fusion protein of US 5,618,699, and the nucleic acid of US 6,127,601, with a reasonable expectation of success. One skilled in the art would have been motivated to generate the claimed invention with a reasonable expectation of success, especially in, especially in the absence of evidence to the

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contrary. Accordingly, the claimed invention is *prima facie* obvious in view of the prior art.

*Remarks*

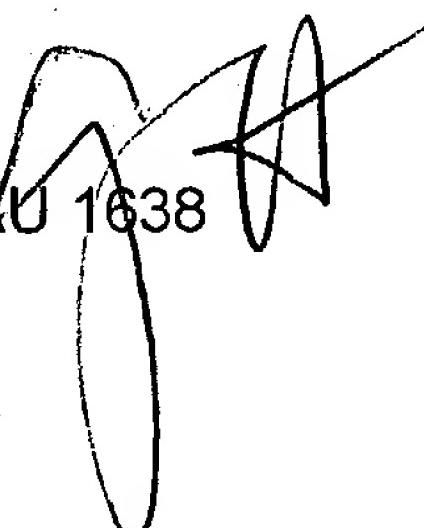
7. No claims are allowed. Claims 23 and 24 are free of the prior art of record.

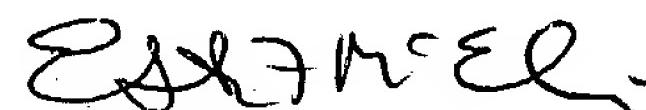
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Georgia L. Helmer whose telephone number is 571-272-0796. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on 571-272-0804. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Georgia Helmer PhD  
Patent Examiner  
Transgenic Plants – AU 1638  
14 December 2004



  
ELIZABETH MC ELWAIN  
PRIMARY EXAMINER